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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/983,474	06/30/1998	DAVID KLATZMANN	31649-134353	1470

7590 03/16/2005

VENABLE
POST OFFICE BOX 34385
WASHINGTON, DC 20005-3917

EXAMINER	
GALVEZ, JAMES JASON	
ART UNIT	**PAPER NUMBER**
1647	28

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/983,474	KLATZMANN ET AL.	
	Examiner	Art Unit	
	J. Jason Galvez	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/6/03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20 and 22-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The amendment filed on 2/06/2003 has been entered. Claims 1-17, 20, and 22-26 are pending in the instant application and are under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

Claim Rejections: 35 U.S.C. § 112, 2nd paragraph

The rejection of claims 4-7 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment and arguments.

Claim Rejections/Objections Maintained/New Grounds of Rejection

Claim Rejections: 35 U.S.C. § 102(b)

The rejection of claims 1, 4-12, 17, 20, 23, and 26 under 35 U.S.C. 102(b) as anticipated by WO 91/11461 is maintained for reasons of record in the office action of 16 June 2002. It is noted that Applicant has erroneously included claim 15 in the 35 U.S.C. § 102(b) rejection. This claim was not originally rejected under 35 U.S.C. § 102(b), but is newly rejected under 35 U.S.C. § 102(b), see below.

Applicant argues reference WO 91/11461 does not anticipate the instant invention. Applicant's argument is based on the assertion that reference WO 91/11461 and the reference incorporated (Hillarp et al., incorrectly referred to at Hillard et al.) do not disclose "a recombinant multimeric peptide that comprises a polypeptide fusion

monomer B". Applicant argues there no evidence that the 45 kDa protein is the β chain of C4bp. Finally, Applicant requests the rejection be withdrawn.

Applicant's arguments have been fully considered and are not found persuasive. Reference WO 91/11461 clearly states the "invention also relates to multimeric C4bp fusion proteins comprising monomeric C4bp fusion polypeptides" (p. 5: lines 21-23). Additionally, the β chain of C4bp is disclosed by reference (p. 4: lines 12-17). Although, the β chain of C4bp was not specifically disclosed as being cloned at that time, the clone was thereafter shortly published by Hillarp et al. (Hillarp et al., Proc Natl Acad Sci 1990, Vol. 87(3): pp. 1183-1187). Hillarp et al. also disclosed a 7:1 ratio of A/B monomers, as is claimed in claim 3 of the instant invention, providing further evidence that the β chain of C4bp was known well before the instant invention (p. 1186: Figure 6). Evidentiary support exists for the β chain of C4bp being known and cloned prior to the instant invention. Furthermore, Applicant's own disclosure states that Hillarp et al. discovered the β chain, citing the reference above, of C4bp as early as 1990 (p. 1: lines 27-32).

Claims 13, 15, and 16 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Pasek et al. (WO 91/11461). Pasek et al. teach that "hetero-multimeric C4bp fusion protein" can be made recombinantly using host cells (p. 27: lines 17-35 to p. 28: lines 1-2).

Claim Objections

The objection to claims 2, 3, 13-16, 22, 24, and 25 as depending from rejected claims is maintained for reasons of record in the office action of 16 June 2002.

Applicant argues that rejected claims are in condition of allowance. Applicant request objection to claims, on the basis of dependency on rejected claims, is withdrawn.

Applicant's arguments have been fully considered and are not found persuasive. For the reasons set forth above, the claims still depend from non-allowed claims. Objection to the claims is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 20, 22-26 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fusion proteins comprising selected CD lymphocyte surface proteins, does not reasonably provide enablement for fusion proteins comprising fragments and all CD lymphocyte surface proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-9, 12-17, 20, 22-26 are drawn to a "fragment" and/or a "heterologous" molecule of an unidentified protein, as well as fragments of C4bp that need not have any particular function. The claim is broad and encompasses molecules that Applicant does not have, which would render the invention not possible from an enablement perspective, i.e. make and/or use the claimed polypeptides. Additionally, there is no function asserted for the claimed fragments or heterologous sequences, which again fails to meet enablement requirements because a person of ordinary skill the art would not know how to use the invention without any ascribed function. Furthermore, the invention encompasses molecules that may or may not be operable within the framework of the present invention due to broad nature of the claims. For example, do any and all fragments and heterologous sequences have use in the present invention? Thus, it would not be possible to make and/or use the invention commensurate in scope due to the quantity of experimentation necessary, the lack of direction presented, the unpredictability in the art, the nature of the invention, and the breadth of the claims.

Claims 4-7 are drawn to "CD lymphocyte surface proteins". "CD lymphocyte surface proteins" encompass a myriad of molecules that may or may not be operable or have the desired effect within the present invention. "CD lymphocytes surface proteins" are a diverse set of molecules with divergent expression and/or function. For example, CD 32 plays a critical role in the removal of antigen-antibody complexes, whereas CD58 can function to stimulate the release of IL-1 (Horst Ibelgaufts, Dictionary of Cytokines 1985, VCH Publishers Inc., pp. 123 and 126). Thus, it would not be possible to make and/or use the invention commensurate in scope due to the quantity of experimentation

necessary, the lack of direction presented, the nature of the invention, and the breadth of the claims.

Claims 10 and 11 are drawn to "a ligand selected from the group consisting of an antigen, a therapeutic enzyme, a CD 35, CR1, and antibody, and any fragment thereof which possesses the ligand property of the whole ligand molecule, and monomer B comprises an antibody or a fragment thereof which has retained its epitope". Applicant is claiming molecules that may or may not be operable within the framework of the present invention due to broad nature of the claims. For example, do all of the recited ligands have the desired effect of the claimed invention? Thus, it would not be possible to make and/or use the invention commensurate in scope due to the quantity of experimentation necessary, the lack of direction presented, the unpredictability in the art, the nature of the invention, and the breadth of the claims.

Claims 1-17, 20, and 22-26 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-9, 12-17, 20, 22-26 are drawn to a "fragment" and/or a "heterologous" molecule of unidentified proteins. The claims are broad and encompass many molecules because a fragment as claimed would need to include only one similar constituent and claimed heterologous molecules to the α or β chain encompass a myriad of molecules only excluding those specified chains. Therefore, Applicant's

recitation "fragment" and "heterologous" is drawn to a genus of molecules. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. Since Applicant has provided no required structures, properties, or functions, a person of ordinary skill in the art cannot envision the claimed genus of molecules and thus, fails to meet written description requirements.

Claims 10 and 11 are drawn to "a ligand selected from the group consisting of an antigen, a therapeutic enzyme, a CD 35, CR1, and antibody, and any fragment thereof which possesses the ligand property of the whole ligand molecule, and monomer B comprises an antibody or a fragment thereof which has retained its epitope". Applicant it claiming a genus of molecules without any designated function. For example, "therapeutic enzymes" encompass a vast set of molecules ranging from synthetic enzymes to natural enzymes, displaying diverse and divert functions. Since Applicant has provided no required structures, properties, or functions, a person of ordinary skill in the art cannot envision the claimed genus of molecules and thus, fails to meet written description requirements.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D**. whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JJG
12/20/2004